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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,462	11/08/2001	Laurence S. Sloman	A01P1083	8664

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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3762	5

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,462	SLOMAN, LAURENCE S.	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4* is/are allowed.

6)☒ Claim(s) *5-11,13,15,16,18 and 20* is/are rejected.

7)☒ Claim(s) *12,14,17 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the automatic capture detection function" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitations "the control circuitry" in line 1, and "the evoked response detection algorithm" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitations "the control circuitry" in line 1, "the evoked response detection algorithm" in line 2, and "the position set of parameter values" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the position set of parameter values" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitations "the control circuitry" in line 1, "the automatic capture detection function" in line 2, and "the orientation of the patient" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 6 is rejected under 35 U.S.C. 102(e) as being anticipated by Park et al. (6,738,666).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 6, Park et al. shows an implantable cardiac device comprising a memory (260) configured to store plural sets of parameter values corresponding to various patient states; a sensor (272) that is operative to generate one or more signals indicative of a patient state; and a controller (220) that is operative to receive the one or more signals from the sensor, process the one or more signals to determine the patient state, and use the corresponding set of parameter values to process sensed electrical activity (Col. 10, line 44-Col. 11, line 15).

5. Claims 6, 11, 13, 15-16, 18, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll (6,445,949).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 6, Kroll shows an implantable cardiac device comprising a memory (44) configured to store plural sets of parameter values corresponding to various patient states (VT1 and BRI corresponds to a normal sinus rhythm, VT1 and VT2 corresponds to a slow ventricular tachycardia, VT2, and VFI correspond to a fast tachycardia, and VFI corresponds to ventricular fibrillation); a sensor (42) that is operative to generate one or more signals (VRI) indicative of a patient state; and a controller (22) that is operative to receive the one or more signals (VRI) from the sensor, process the one or more signals (VRI) to determine the patient state, and use the corresponding set of parameter values to process sensed electrical activity (Figs. 1-2, 5A-5C, ; Col. 5, line 66-Col. 9, line 38).

With respect to claim 11, Kroll shows a method for modifying a detection algorithm comprising receiving one or more signals (VRI) indicative of a patient state; processing the one or more signals (VRI) to determine the patient state (bradycardia, normal sinus rhythm, slow VT, fast VT, or fibrillation); and modifying the detection algorithm (parameters VT1, VT2, VFI) based on the determined patient state (Figs 2, 5A-5C; Col. 5, line 66-Col. 9, line 38).

Regarding claim 13, Kroll shows the receiving one or more signals comprises receiving one or more activity signals (VRI – activity of the heart).

With respect to claim 15, Kroll further shows providing plural sets of parameter values corresponding to various patient states (VT1 and BRI corresponds to a normal sinus rhythm, VT1 and VT2 corresponds to a slow ventricular tachycardia, VT2, and VFI correspond to a fast tachycardia, and VFI corresponds to ventricular fibrillation), and wherein modifying the detection algorithm (steps 318-320, steps 322-324, steps 340-342, 344-346, steps 366-368, steps 368-370-372) further comprises using the corresponding set of parameter values based on the determined patient state (Figs 2, 5A-5C; Col. 5, line 66-Col. 9, line 38).

Regarding claim 16, Kroll shows an implantable cardiac device comprising: a sensor that is operative to generate one or more signals indicative of a patient state (step 206, step 302); and a controller that is in communication with the sensor, the controller being programmed to apply a detection algorithm to received electrical activity signals, wherein the controller is operative to receive the one or more signals from the sensor, process the one or more signals to determine the patient state, and adjust one or more parameter values (steps 318-320, steps 322-324, steps 340-342, 344-346, steps 366-368, steps 368-370-372) of the detection algorithm based on the determined patient state (Figs 2, 5A-5C; Col. 5, line 66-Col.. 9, line 38).

With respect to claim 18, Kroll shows the sensor comprises an activity sensor (one that measures heart activity).

Regarding claim 20, Kroll further shows the controller is operative to maintain a plurality of sets of parameter values corresponding to the respective patient states (VT1 and BRI corresponds to a normal sinus rhythm, VT1 and VT2 corresponds to a slow ventricular tachycardia, VT2, and VFI correspond to a fast tachycardia, and VFI corresponds to ventricular fibrillation) and wherein the controller adjusts the detection algorithm by using one of the sets of

parameter values based on the detected patient state (Figs 2, 5A-5C; Col. 5, line 66-Col. 9, line 38).

Allowable Subject Matter

6. Claims 1-4 are allowed.

7. Claims 5, and 7-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. Claims 12, 14, 17, and 19 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 1-5, the prior art of record fails to teach or suggest a method comprising receiving one or more signals from a sensor processing the one or more signals to determine a patient state and *modifying the evoked response detection algorithm based on the detected patient state.*

Regarding claims 7-9, the prior art of record fails to teach or suggest an implantable cardiac device comprising a memory configured to store plural sets of parameter values corresponding to various patient states; a sensor that is operative to generate one or more signals indicative of a patient state; and a controller that is operative to receive the one or more signals from the sensor, process the one or more signals to determine the patient state, and use the corresponding set of parameter values to process sensed electrical activity, all in combination with the controller configured to modify the detection algorithm by retrieving a position set

comprising a plurality of parameter values pertaining to the orientation of the patient; and calibrating the detection algorithm using the position set of parameter values.

With respect to claim 10, the prior art of record fails to teach or suggest an implantable cardiac device comprising a memory configured to store plural sets of parameter values corresponding to various patient states; a sensor that is operative to generate one or more signals indicative of a patient state; and a controller that is operative to receive the one or more signals from the sensor, process the one or more signals to determine the patient state, and use the corresponding set of parameter values to process sensed electrical activity, all in combination with the controller being configured to disable an automatic capture detection function to prevent false loss of capture detection when the signal indicates that an orientation of the patient is changing.

Regarding claims 12, and 14, the prior art of record fails to teach of suggest a method for modifying a detection algorithm comprising receiving one or more signals indicative of a patient state; processing the one or more signals to determine the patient state and modifying the detection algorithm based on the determined patient state all in combination with the receiving of one or more signals comprising receiving one or more position signals.

With respect to claims 17, and 19, the prior art of record fails to teach of suggest an implantable cardiac device comprising: a sensor that is operative to generate one or more signals indicative of a patient state; and a controller that is in communication with the sensor, the controller being programmed to apply a detection algorithm to received electrical activity signals, wherein the controller is operative to receive the one or more signals from the sensor, process the one or more signals to determine the patient state, and adjust one or more parameter

values of the detection algorithm based on the determined patient state, all in combination with the sensor comprising a position sensor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am -6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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